CLAIMS

1. A process for the preparation of aqueous suspensions to be used in pharmaceutical formulations for inhalation by nebulisation, which comprises the following steps:

   a) adding one or more active ingredients in the form of a sterile micronised powder to an aqueous solution constituting the vehicle in a turboemulsifier equipped with a high-power turbine and connected to a loading hopper by introducing said active ingredients through the turbine after having applied the vacuum;

   b) homogenising the active ingredient in the suspension, still under vacuum, using the turbine system;

   c) distributing the suspension thus obtained into suitable containers such as monodose vials.

2. A process as claimed in claim 1, wherein the aqueous solution constituting the vehicle contains additives or excipients selected from wetting, stabilising, isotonic and/or buffer agents.

3. A process as claimed in claims 1 or 2 wherein the active ingredient is a corticosteroid.

4. A process as claimed in claims 1-3 wherein the aqueous solution constituting the vehicle has been sterilised by heat or filtration.

5. A process as claimed in claims 1-4, wherein the preparation is performed under sterile conditions by adding a micronised corticosteroid, sterilised by irradiation or heating.

6. A process as claimed in claims 1-5, wherein the corticosteroid is micronised beclomethasone dipropionate sterilised by gamma radiation.

7. A process as claimed in claims 1 to 6, wherein the homogenisation stage is conducted at a speed of between 750 and 4000 rpm for 5 to 60

minutes.

8. A process as claimed in claim 7, wherein the homogenisation stage is conducted at a speed of between 1600 and 3000 rpm for 20 to 40 minutes.

9. A process as claimed in claim 7, wherein the homogenisation stage is conducted at a speed of 2900 rpm for 30 minutes.

10. A process as claimed in claims 1 to 9, wherein the Feret diameter of at least 90% of the particles is less than or equal to 8 μm.

11. Pharmaceutical formulations to be administered by nebulisation, containing aqueous suspensions obtained with the process claimed in claims 1 to 10.

12. Pharmaceutical formulations as claimed in claim 11, wherein the active ingredient is a corticosteroid selected from BDP, mometasone furoate, flunisolide, budesonide, fluticasone propionate or ciclesonide.

13. Pharmaceutical formulations as claimed in claim 12, wherein the concentration of active ingredient is between 0.01 and 0.1% w/v.

14. Pharmaceutical formulations as claimed in any one of claims 9 to 13 in unit dose preparations which are pre-formed or produced with the "blow, fill and seal" technology.

15. Pharmaceutical formulations in the form of aqueous suspension to be administered by nebulization comprising as active ingredient a micronised sterile corticosteroid wherein the median volumetric diameter of the 90% of the particles is less than 8 μm and that of 50% of the particles is comprised between 2 and 3.5 μm as determined by using a Malvern apparatus.

16. Pharmaceutical formulations according to claim 15 wherein the median volumetric diameter of the 90% of the particles is less than 7 μm and that of the 50% of the particles is comprised between 2.5 and 3 μm.

17. Pharmaceutical formulations according to claims 15 and 16 wherein the micronized sterile corticosteroid is beclometasone dipropionate.

18. Pharmaceutical formulations as claimed in claims 15 to 17, for the treatment of lung diseases such as asthma and chronic bronchitis through an once-a-day administration.